

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

EURICA CALIFORNIAA,

Plaintiff,

v.

ANDREW HIRSHFELD,¹

Performing the Duties of Under
Secretary of Commerce for
Intellectual Property and Deputy
Director of the United States Patent
and Trademark Office,

Defendant.

Civil No. 1-20-cv-00985-MSN-TCB

MEMORANDUM OPINION

This matter comes before the Court on plaintiff Eurica Californiaa's Motion for Summary Judgment (Dkt. No. 11) and defendant Andrew Hirshfeld's Cross Motion for Summary Judgment (Dkt. No. 13). This action arises from plaintiff's challenge to the United States Patent and Trademark Office's ("USPTO") patent term adjustment ("PTA") determination for United States Patent No. 10,245,075 (the "'075 patent"). The parties' competing positions on the merits of the USPTO's PTA determination have been fully briefed, making their motions ripe for disposition. For the reasons that follow, the Court will DENY plaintiff's motion and GRANT defendant's cross motion.

¹ Andrew Hirschfeld is performing the functions and duties of the Under Secretary of Commerce for the Intellectual Property and Deputy Director of the United States Patent and Trademark Office and is automatically substituted as a party pursuant to Fed. R. Civ. P. 25(d).

BACKGROUND

When an applicant files a patent application with the USPTO, a USPTO patent examiner reviews the application—a process known as “examination”—to determine whether to issue a patent. *See 35 U.S.C. § 131.* Examiner and applicant go through a series of back and forth edits until the examiner determines the claims should be rejected or accepted. *Pfizer, Inc. v. Lee*, 811 F.3d 466, 475–76 (Fed. Cir. 2016). If the examiner determines a patent is warranted, the examiner issues a “Notice of Allowability” that sets out the terms of the patent that will subsequently be issued. Def. Mem. (Dkt. No. 14) at 5 (citing *Manual of Patent Examining Procedure* at ¶ 1302.03). The USPTO also provides the applicant with a more formal “Notice of Allowance” that identifies additional fees owed before a patent can issue. *Id.* (citing *Manual of Patent Examining Procedure* at ¶ 1303). At this point, examination and prosecution of the patent are complete, unless the examination is reopened on the merits. *See Novartis AG v. Lee*, 740 F. 3d 593, 602 (Fed. Cir. 2014). If an applicant is dissatisfied with the patent claims laid out in the Notice of Allowance, the applicant may file a request to amend the claims under 37 C.F.R. § 1.312. *See* Def. Mem. at 5–6. This “after allowance” amendment effectively reopens the patent examination process. In simplified terms, once the amendment is addressed and there are no additional changes to the patent application, the patent is issued.

A patent term, *i.e.* the length of time the patent is enforceable, is calculated starting from the day the application is submitted to the USPTO. When determining the patent term, the USPTO accounts for delays caused by either the examiner or applicant that may have occurred during examination. For example, there are three types of statutorily-required adjustments to the patent term when the USPTO fails to meet benchmarks in the examination process or an applicant successfully challenges a negative patent eligibility determination. *See generally 35 U.S.C. §*

154(b)(1).² The USPTO is also statutorily required to account for delays in the patent examination “during which the applicant failed to engage in reasonable efforts to conclude [prosecution, processing, or examination] of the application.” 35 U.S.C. § 154(b)(2)(C).

The PTA is the sum of the delays caused by the USPTO and the applicant. *See Intracellular Therapies, Inc. v. Iancu*, 938 F.3d 1371, 1374 (Fed. Cir. 2019) (discussing PTA adjustments). The patent term is increased if delays were due to the USPTO or decreased if due to the applicant. If an applicant is dissatisfied with the PTA determination, the applicant may file a request for reconsideration. *See* 35 U.S.C. § 154(b)(3)(B)(ii). If the applicant is still dissatisfied with the PTA determination after reconsideration, the applicant may seek Article III review in this Court. *See id.* § 154(b)(4)(A).

PROCEDURAL HISTORY

Plaintiff owns the ‘075 patent issued on April 2, 2019. In calculating the PTA for ‘075, the USPTO released an Issue Notification on March 13, 2019, which included a PTA of 1,018 days. Admin. Record (Dkt. No. 7-3) at 130. That PTA calculation was based in part on a finding that the applicant was responsible for 51 days of delay during the patent’s prosecution under 37 C.F.R. § 1.704(c)(10). The USPTO tied these 51 days of delay to an amendment plaintiff filed pursuant to 37 C.F.R. § 1.312 after he received the ‘075 patent’s Notice of Allowance. *Id.* at 142.

Plaintiff filed a request for reconsideration on April 3, 2019, asking that the USPTO recalculate the ‘075 patent’s PTA at 1,069 days. *Id.* at 139. In support, plaintiff argued that he was required to file the Section 1.312 amendment in response to an “Examiner’s Amendment” that

² An “A delay” occurs when the examiner fails to send a Notice of Allowance within fourteen (14) months after an application is filed. *See* 35 U.S.C. § 154(b)(1)(A)(i)(I). A “B delay” occurs when the USPTO fails to issue a patent within “three years after the actual filing of the application in the United States.” *Id.* § 154(b)(1)(B). Lastly, a “C delay” is caused when the patent applicant is successful in challenging an administrative or judicial decision. *See id.* § 154(b)(1)(C). Any days that overlap between an A, B, and C delay are deducted from the PTA determination. *See id.* § 154(b)(2)(A).

appeared for the first time in the ‘075 patent’s Notice of Allowance. *Id.* at 142. Plaintiff further asserted that because he had no other way to address that “Examiner’s Amendment,” he should not be penalized for filing a *responsive* Section 1.312 amendment. *Id.* The USPTO disagreed and denied plaintiff’s request on March 30, 2020. *See id.* at 138–145. This action followed pursuant to 35 U.S.C. § 154(b)(4). *See id.* at 139; Compl. (Dkt. No. 1) at ¶¶ 17–19.

LEGAL STANDARD

Summary judgment is proper where, viewing the facts in a light most favorable to the non-moving party, there remains no genuine issue of material fact and the evidence demonstrates the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986); *Evans v. Techs. Applications & Serv. Co.*, 80 F.3d 954, 958–59 (4th Cir. 1996). A party opposing a motion for summary judgment must respond with specific facts, supported by proper documentary evidence, showing that a genuine dispute of material fact exists, and that summary judgment should not be granted in favor of the moving party. *Anderson*, 477 U.S. at 250.

Under 35 U.S.C. § 154 this Court applies its Rule 56 standard in consideration of the APA’s judicial review provisions. *See* 35 U.S.C. § 154(b)(4)(A) (“Chapter 7 of title 5 shall apply to” an action brought by an applicant dissatisfied with the USPTO’s decision on a request for reconsideration; chapter 7 of title 5, in turn, refers to the judicial review provision of the Administrative Procedure Act (“APA”)). When reviewing under the APA, this Court shall uphold the USPTO’s actions, findings, and conclusions under the regulation unless they are found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” *See Pfizer, Inc.*, 811 F.3d at 471. This standard “is the most deferential of the APA standards of review, and is only met where a reviewing court can conclude with definite and firm conviction that a clear

error of judgment or a mistake has been committed.” *President & Fellows of Harvard Coll. v. Lee*, 589 F. App’x. 982, 986 (Fed. Cir. 2014) (internal citations and quotations omitted). Under the APA, “the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.” *Buckingham v. Mabus*, 772 F. Supp. 2d 295, 300 (D.D.C. 2011).

DISCUSSION

Plaintiff challenges the USPTO’s decision to include 51 days of applicant’s delay in its PTA for the ‘075 patent. *See* Compl. at ¶ 22. Plaintiff primarily requests a full reduction of that applicant’s delay and alternatively seeks a partial reduction of the same. *Id.* at ¶¶ 23–24. Plaintiff pursues both theories at summary judgment by arguing there is no dispute of material fact as to the dates or content of the relevant office actions and responses thereto, and therefore the only issues to be resolved are issues of law. *See* Pl. Br. (Dkt. No. 12) at 12.

Defendant agrees that the case is appropriate for resolution at summary judgment but disputes plaintiff’s application of the law. *See* Def. Mem. at 2, 12–13 (quoting *R.R. Donnelley & Sons Co. v. Dickinson*, 123 F. Supp. 2d 456, 458 (N.D. Ill. 2000)).

To resolve both motions, the Court must determine whether the USPTO acted arbitrarily and capriciously in determining plaintiff’s filing of an after allowance amendment did not constitute a “reasonable effort to conclude processing or examination” of his patent application under 35 U.S.C. § 154(b)(2)(C).

A. 37 C.F.R. § 1.704(c)(10) and the Prior Proceedings

Congress delegated authority to the USPTO to promulgate regulations that would establish circumstances in which an applicant fails to engage in “reasonable efforts to conclude processing or examination of [his patent] application.” 35 U.S.C. § 154(b)(2)(C). So as not to engage in a

case-by-case determination of each application, the USPTO promulgated regulations outlining actions that are “strict examples” of unreasonable efforts. *See* 65 Fed. Reg. at 56378–79. Specifically at issue here, 37 C.F.R. § 1.704(c)(10) states,

Circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application . . . include . . . [s]ubmission of an amendment under § 1.312 or other paper, other than an amendment under § 1.312 or other paper expressly requested by the Office or a request for continued examination in compliance with § 1.114, after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date of mailing of the notice of allowance under 35 U.S.C. § 151 and ending on the date the amendment under § 1.312 or other paper was filed.

In denying plaintiff’s request for redetermination of the ‘075 patent’s PTA, the USPTO explicitly relied on this language—finding (a) the 51-day delay plaintiff challenged was due to his filing of an amendment under 37 C.F.R. § 1.312, and (b) that “an amendment under 37 C.F.R. § 1.312 after allowance, is a paper that *is* considered a failure to engage in reasonable efforts to conclude processing or examination of an application.” Admin. Record at 144 (emphasis in original).

B. This Court’s Review

Plaintiff challenges the USPTO’s application of 37 C.F.R. § 1.704(c)(10) by arguing the USPTO exceeded its regulatory authority to the extent it adopted and then interpreted a regulation that prevented the USPTO from considering exceptional circumstances when determining the ‘075 patent’s PTA. Pl. Br. at 22–23. Plaintiff supports this position by arguing that he faced extraordinary circumstances when the examiner presented changes to plaintiff’s claims for the first time in the Notice of Allowance. *Id.* at 17–20; Admin. Record at 144 (“[t]he filing of the amendment under 37 C.F.R. 1.312 is not a basis for a reduction . . . because it is the ‘only procedure available for an applicant to suggest changes to an Examiner’s amendment . . . presented for the

first time in a notice of allowance’’’). Therefore, plaintiff concludes that he is entitled to an exception under 37 C.F.R. § 1.704(c)(10) and challenges the USPTO’s failure to recognize as much. *Id.*

Defendant responds that the USPTO’s regulations are entitled to *Chevron* deference because 37 C.F.R. § 1.704(c)(10) is properly promulgated under the authority delegated to it by Congress in 35 U.S.C. § 154. *See* Def. Mem. at 24–27. Defendant further argues that plaintiff’s after allowance amendment is a failure to engage in reasonable efforts to conclude processing or examination because it firmly falls within the language of the regulation. *See id.* (citing 37 C.F.R. § 1.704(c)(10)). Therefore, defendant claims the USPTO did not err in assessing applicant delay to the ‘075 patent, nor commit a “clear error in judgment.” Def. Reply (Dkt. No. 26) at 2.

“When reviewing an agency’s statutory interpretation, this court applies the two-step framework established in *Chevron*.” *See Gilead Scis., Inc. v. Lee*, 778 F.3d 1341, 1345 (Fed. Cir. 2015). However, the *Chevron* framework applies only when “it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.” *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). The statute at issue provides, “[t]he Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” 35 U.S.C. § 154(b)(2)(C)(iii). Thus, it is clear from the face of the statute that Congress has provided the USPTO with express authority to promulgate 37 C.F.R. § 1.704(c)(10). *See Gilead Scis., Inc.*, 778 F.3d at 1346-49 (engaging in a *Chevron* analysis of 35 U.S.C. § 154). As such, the *Chevron* framework applies, and the Court must apply it.

Chevron step one asks whether Congress “directly addressed the precise question at issue.” *Gilead Scis., Inc.*, 778 F.3d at 1346. If not, the Court then determines in *Chevron* step two whether the agency’s interpretation is based on a permissible construction of the statute. *Nuclear Energy Inst., Inc. v. Env’t Prot. Agency*, 373 F.3d 1251, 1269 (D.C. Cir. 2004).

The precise question at issue here is whether an amendment, filed after prosecution has concluded, that responds to an examiner’s amendment filed with the Notice of Allowance, constitutes a “failure to engage in reasonable efforts to conclude processing or examination of an application” such that applicant delay would accrue under the PTA statute. *See* 35 U.S.C. § 154(b)(2)(C)(iii). Plaintiff argues that the term “reasonable” is unambiguous. Pl. Resp. (Dkt. No. 23) at 37. Defendant, however, argues it is ambiguous and that the statute does not identify whether the USPTO should consider applicants’ efforts generally, or whether it must engage in an *ad hoc* determination for every application. Def. Reply at 5. Because nothing in the language of the PTA statute addresses what constitutes “reasonable efforts” when an applicant files an amendment post-Notice of Allowance, the Court finds the statute ambiguous and does not answer the question at issue here. Accordingly, the Court’s analysis must proceed to *Chevron* step two.

Chevron step two requires the Court to determine “whether the [USPTO’s] answer is based on a permissible construction of the statute.” *Gilead Scis., Inc.*, 778 F.3d at 1349. When Congress expressly directs an agency to promulgate regulations, “judicial deference to an agency’s construction of a statutory scheme is afforded considerable weight,” *id.*, and will be upheld unless it is found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” *See Pfizer, Inc.*, 811 F.3d at 471.

Here, Congress explicitly delegated the authority to the USPTO to “prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable

efforts to conclude processing or examination of an application.” 35 U.S.C. § 154(b)(C)(iii). The USPTO exercised its congressionally delegated authority by promulgating 37 C.F.R. § 1.704(c)(10). While plaintiff’s interpretation—that filing an after allowance amendment in response to an examiner’s amendment in the Notice of Allowance constitutes a “reasonable effort” to conclude prosecution of the patent application—is arguably a plausible one, nothing in the plain language of the statute commands that understanding of what conduct constitutes “reasonable efforts” by an applicant following a Notice of Allowance. *Intra-Cellular Therapies, Inc.*, 938 F.3d at 1380. Courts that have examined the issue have held that the term “reasonable efforts” “focuses on applicant conduct as opposed to the results of such conduct,” *Gilead Scis., Inc.*, 778 F.3d at 1347, and the USPTO has determined that an after allowance amendment filed under 37 C.F.R. § 1.312 is unreasonable conduct. Thus, the Court will defer to the USPTO’s regulations regarding the assessment of PTA reduction for applicant delay under 37 C.F.R. § 1.704(c)(10).

Having concluded the regulation is entitled to *Chevron* deference, the Court now applies APA standards of review and will only overturn the USPTO’s PTA determination if the Court finds the USPTO’s decision was arbitrary and capricious. According to the administrative record, the applicant filed an amendment under 37 C.F.R. § 1.312 after the mailing of the Notice of Allowance. Admin. Record at 143. The USPTO determined that under 37 C.F.R. § 1.704(c)(10), the filing of the amendment under 37 C.F.R. § 1.312 in this instance constituted a failure to engage in reasonable efforts. Admin. Record at 144. Further, the USPTO found 37 C.F.R. § 1.704(c)(10) “does not provide for an exception to reduction of PTA for the filing of an amendment under 37 C.F.R. § 1.312 where an applicant finds the changes and/or additions made by an examiner’s amendment unacceptable.” Admin. Record at 144 (the USPTO previously considered and rejected the possibility of an exception during the rulemaking process for 37 C.F.R. § 1.704(c)(10)).

Because the applicant's filing of an after allowance amendment was clearly considered a failure to engage in reasonable efforts under 37 C.F.R. § 1.704(c)(10), and the regulation did not provide for an exception for responding to an examiner's amendment filed with the Notice of Allowance, the Court finds 51 days of applicant delay was not arbitrary and capricious.³

CONCLUSION

This Court finds that the Patent Office's determination of applicant delay is supported by a permissible reading of the PTA statute and that the determination was not arbitrary and capricious. This Court has considered plaintiff's remaining arguments and finds them unpersuasive. Accordingly, this Court finds that summary judgment should be granted in favor of defendant. Plaintiff's motion for summary judgment is denied.

An appropriate order shall issue.

/s/

Hon. Michael S. Nachmanoff
United States District Judge

Alexandria, Virginia
December 30, 2021

³ Plaintiff's alternative request for a partial reduction of the 51-day calculation similarly fails because Plaintiff did not raise the issue of reducing the PTA determination by a lesser amount in his PTA petition and the USPTO could not have anticipated that plaintiff would make this argument. Plaintiff only made two arguments in his petition: (1) 37 C.F.R. 1.704(c)(10) does not apply and (2) justice requires an exception to the regulation. Admin. Record at 132. At no point did plaintiff assert that the *amount* of applicant delay was too high, only that there should be no applicant delay at all. The USPTO was not on notice of plaintiff's argument and could not have surmised it based on the arguments before it in his petition. Therefore, plaintiff waived his ability to raise in district court any argument for a lesser applicant delay amount. *See Nuclear Energy Inst., Inc. v. Env't Prot. Agency*, 373 F.3d 1251, 1297 (D.C. Cir. 2004) ("Issues not raised before an agency are waived and will not be considered by a court on review."); *Rocky Mountain Health Maint. Org., Inc. v. Price*, 297 F. Supp. 3d 152, 158 (D.D.C. 2018) ("argument is preserved if the agency reasonably should have understood the full extent of the plaintiff's argument." (internal quotations omitted)); *Buckingham v. Mabus*, 772 F. Supp. 2d 295, 300 (D.D.C. 2011) (review of PTA determination is limited to the administrative record and the arguments presented before the agency).